DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0965]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. Members will participate via teleconference. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 14 through 15, 2021, from 8:30 a.m. to 5 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by October 13, 2021. Comments received on or before October 12, 2021, will be provided to the committee. Comments received after October 12, 2021, and by October 13, 2021, will be taken into consideration by FDA.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following separate links on the days of the meeting:

Day 1: https://youtu.be/BhlshZ7Lkr0.

Day 2: https://youtu.be/c-H40GrvWz4.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0965. The docket will close on October 13, 2021. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 13, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications, submissions, or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0965 for ''Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Prabhakara Atreya or Kathleen Hayes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993–0002, 240–818–7798, via email at *CBERVRBPAC@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/advisory-committees* and scroll down to the appropriate advisory committee meeting link, or call the

advisory committee information line to learn about possible modifications before joining the meeting.

SUPPLEMENTARY INFORMATION: Consistent with FDA's regulations, this notice is being published with less than 15 days prior to the date of the meeting based on a determination that convening a meeting of the Vaccines and Related Biological Products Advisory Committee as soon as possible is warranted. This **Federal Register** notice could not be published 15 days prior to the date of the meeting due to recent requests to amend the Emergency Use Authorization (EUA) of the Moderna COVID–19 mRNA vaccine for the administration of a booster dose, following completion of the primary series, to individuals 18 years of age and older, and also the EUA of the Janssen Biotech Inc. COVID–19 vaccine for the administration of a booster dose, to individuals 18 years of age and older, and the need for prompt discussion of such requests given the COVID–19 pandemic.

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 14, 2021, under Topic 1, the committee will meet in open session to discuss the EUA of the Moderna COVID–19 mRNA vaccine for the administration of a booster dose, following completion of the primary series, to individuals 18 years of age and older. On October 15, 2021, under Topic II, the committee will meet in open session to discuss the EUA of the Janssen Biotech Inc. COVID–19 vaccine for the administration of a booster dose, to individuals 18 years of age and older.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/advisory-committees/advisory-committee-calendar.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 12, 2021, will be provided to the committee. Comments received after October 12, 2021, and by October 13, 2021, will be taken into consideration by FDA. Oral presentations from the public will be scheduled approximately between 12:45 p.m. and 1:45 p.m. Eastern Time on October 14, 2021, and approximately between 11 a.m. and 12 noon Eastern Time on October 15, 2021. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before 6 p.m. October 8, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 12, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Prabhakara Atreya or Kathleen Hayes (*CBERVRBPAC@fda.hhs.gov*) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: *https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 5, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–22037 Filed 10–5–21; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0271]

Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Revised Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry entitled ''Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act'' (''revised draft guidance''). This revised draft guidance, when finalized, will describe how FDA intends to apply certain provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to human drug products compounded by State-licensed pharmacies that are not outsourcing facilities and distributed for use within a hospital or health system. First, it addresses the requirement that compounding be based on the receipt of a valid prescription order for an identified individual patient. Second, it addresses the provision concerning compounded drug products that are essentially copies of a commercially available drug product. This draft guidance revises the draft guidance issued in 2016 entitled, ''Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act'' (''draft guidance''). FDA is revising the draft guidance to address stakeholder feedback and provide further clarification on policies regarding hospital and health system compounding. This revised draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the revised draft guidance by December 6, 2021 to ensure that the Agency considers your comment on this revised draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the revised draft guidance by December 6, 2021.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way: